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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,937	04/14/2000	Michael B Chancellor	28682-501-CIP	9119

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/549,937	Applicant(s) CHANCELLOR ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 220,222 is/are allowed.
- 6) ☒ Claim(s) 107,110-112,114,154,157-161,163,166-170,173-178,180-183,190,193-197,199-201,204-206,209-211,216-219,221,223-229 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 107,110-112,114,154,157-161,163,166-170,173-178,180-183,190,193-197,199-201,204-206-209-211,216-229.

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DETAILED ACTION

Final Rejection

Claims 107, 110-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 190, 193-197, 199-201, 204-206, 209-211, and 216-229 are pending.

Applicant's traversal, the amendment to the specification, and the amendment to claims 107, 154, 163, 170, 178, 197, 201, 216, 217, 220, and 222 in paper filed on 10/25/05 is acknowledged and considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 217-218 and 223-229 remain and claim 216 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New matter rejection

The limitation '(b) replating non-adherent cells from step (a) in a second collagen-coated container' in amended claims 107, 154, 163, 170, 178, 216 and claims dependent therefrom is not supported by the instant specification. The limitation is broader than the previous limitation

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for step (b) in the claims. See *In re Wertheim* 541 F. 2d 257, 191 USPQ (CCPA 1976). There appears to be no written description of the claim limitation “(b) replating non-adherent cells from step (a) in a second collagen-coated container’ in the application as filed. See MPEP § 2163.06. Applicant asserts that support for the limitation is found on page 29, lines 14-23 of the instant specification.

Page 29, lines 12-23 recites:

Subsequently, cells were suspended in growth medium (DMEM supplemented with 10% fetal bovine serum, 10% horse serum, 0.5% chick embryo extract, and 2% penicillin/streptomycin). Cells were then preplated in collagen-coated flasks (patent application U.S. Serial No. 09/302,896 of Chancellor et al.). After approximately 1 hour, the supernatant was removed from the flask and re-plated into a fresh collagen-coated flask. The cells which adhered rapidly within this 1 hour incubation were mostly fibroblasts (Z. Qu et al., supra, application U.S. Serial No. 09/302,896 of Chancellor et al.). The supernatant was removed and re-plated after 30-40% of the cells had adhered to each flask. After approximately 5-6 serial 20 platings, the culture was enriched with small, round cells, designated as PP6 cells, which were isolated from the standing cell population and used in further studies. The adherent cells isolated in the early platings were pooled together and designated as PP1-4 cells.

Page 29 is directed to pre-plating cells in collagen-coated flask, wherein cells were preplated into the flask and after 1 hour the supernatant was removed from the flask and re-plated into a fresh collagen-coated flask. The supernatant was removed and replated after 30-40% of the cells adhered to each flask as supported in amended claim 222. Page 29, lines 14-23 does not

explicitly recite the limitation. Thus, one skilled in the art would not consider the broadening of the limitation to be supported in the original disclosure.

The limitation '(c) replating step (b) at least three times' in amended claims 107 and 216 and claims dependent therefrom is not supported by the as-filed specification. The limitation is broader than the previous limitation for step (c) in the claims. See *In re Wertheim* 541 F. 2d 257, 191 USPQ (CCPA 1976). Applicant cites page 29, lines 12-23 for support of the limitation. The disclosure on page 29 does not support repeating step (b) at least three times. Thus, one skilled in the art would not consider the limitation to be supported in the original disclosure.

Applicant's arguments filed 10/25/05 have been fully considered but they are not persuasive.

In response to applicant's argument that page 29, lines 12-23 broadly described replating non-adherent cells and 30-40% of the cells is an example, the argument is not found persuasive because page 29 does not broadly disclose replating non-adherent cells. The description on page 29 is directed to replating cells after 30-40% of the cells from the original cell suspension adhered to the container. It appears that the recitation of "The supernatant was removed and re-plated after 30-40% of the cells had adhered to each flask" is describing the prior sentence "After approximately 1 hour, the supernatant was removed from the flask and re-plated into a fresh collagen-coated flask." and not broadly describing the replating step. See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000)

In response to applicant's argument that the specification incorporates two priority documents which broadly describe re-plating non-adherent cells from one collagen-coated container to a second collagen-coated container (See Example 1 of '896), the argument is not

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found persuasive because Example 1 is limited to replating non-adherent cells after 15-20% of the cells have adhered to the first container. Example 1 does not generically contemplate replating non-adherent cells (after 0.11%-99.9% of cells have adhered to the first container).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 190, 193-197, 199-201, 204-206, 209-211 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "wherein the cells survive over time" in claims 190, 193-197, 199-201, 204-206, 209-211 is a relative term, which renders the claim indefinite. The term "wherein the cells survive over time" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and the skill artisan would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. It is not apparent what time period (4 weeks, 6 months, 10 years, etc.) is being defined by the claims or being compared to.

Applicant's arguments filed 11/21/02 have been fully considered but they are not persuasive. The 112 second paragraph was made in a prior office action based on similar terminology (applicants are citing support for the term on page 16, lines 11-14, which is directed to long-term survivability). The applicant overcame the rejection by deleting the term from the claims. The applicant did not provide arguments with the deletion of the term from the claims.

Response to Arguments

Applicant's arguments, see page 15, filed 10/25/05, with respect to claim objections have been fully considered and are persuasive. The objection of claims 220 and 222 has been withdrawn because of the amendment to the claims.

Applicant's arguments, see page 16, filed 10/25/05, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claims 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 217, 223-226 has been withdrawn because of the amendment to the claims.

Applicant's arguments, see page 16, filed 10/25/05, with respect to 102 rejection have been fully considered and are persuasive. The rejection of claims 107, 114, 216, 218 has been withdrawn because of the amendment to the claims to recite three times to enrich.

Applicant's arguments, see pages 17-22, filed 10/25/05, with respect to 103 rejection have been fully considered and are persuasive. The rejection of claims 190, 193, 194, 196, 197, 199, 201, 204, 206, 209-210, 227 and 228 has been withdrawn because one of ordinary skill in the art would not have been motivated to use skeletal muscle cells to bulk smooth muscle without using applicant's specification for guidance.

Applicant's arguments, see pages 22-23, filed 10/25/05, with respect to double patenting rejection have been fully considered and are persuasive. The rejection of claims 107, 216, 219, and 221 has been withdrawn because of the filing of a terminal disclaimer.

Conclusion

Claims 220 and 222 are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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